

RYAN WHITE TITLE I PROGRAM

**Letter of Medical Necessity for
Antiretroviral Resistance Assays**

Date: _____

As the primary medical caretaker for _____, who has a diagnosis of _____, it is my considered opinion that he/she requires genotypic resistance testing. The patient's prognosis is _____. The following criteria have been met:

1. The patient has sub-optimal suppression of the viral load following initiation of antiretroviral therapy as defined by the current medical guidelines of the Department of Health and Human Services.
2. The patient has failed multiple antiretroviral regimens as defined by the current medical guidelines of the Department of Health and Human Services.

I understand genotypic resistance testing may only be ordered under the following conditions:

1. The above criteria have been met and are fully documented in the patient's medical record;
2. The patient must have been fully adherent to his/her current antiretroviral treatment regimen;
3. Adherence has been discussed with the patient on an on-going basis as part of his/her medical treatment;
4. The patient's plasma HIV RNA (viral load) at the time of testing must be at least 1000 co/ml;
5. The patient must be on antiretroviral medications at the time of testing; and
6. Maximum of two (2) tests may be ordered in any consecutive twelve month period.

Sincerely,

_____, M.D.

Print Physician's name

Florida Medical License # (MEO#)

Patient's 10 digit Medicaid # (if applicable)

Patient's CIS # (assigned by the Ryan White Title I Service
Delivery Information System)

Please note: All questions should be addressed to Mr. Daniel T. Wall, Assistant Director, Office of Strategic Business Management, at (305) 375-4742. Requests for information/clarification of a clinical nature will be forwarded by Miami-Dade County to the Miami-Dade HIV/AIDS Partnership Medical Care Subcommittee and/or a qualified member of the Subcommittee.

Pursuant to Article VI, Section 6.4 (H) of the Ryan White Title I Professional Service Agreement, Miami-Dade County has the right to access all client files (including electronic files), service utilization data, and medical records during on site verification or audit by County personnel and/or authorized individuals to confirm the accuracy of all information reported by the service provider.

Rev. 3/23/05

**RYAN WHITE TITLE I PROGRAM
LETTER OF MEDICAL NECESSITY FOR
ANTIRETROVIRAL HIV GENOTYPE RESISTANCE ASSAYS: TREATMENT INTENT STUDY**

Date: _____

A MAXIMUM OF TWO (2) ANTIRETROVIRAL RESISTANCE TESTS MAY BE ORDERED IN ANY CONSECUTIVE TWELVE (12) MONTH PERIOD TO INCLUDE NO MORE THAN ONE (1) HIV PHENOTYPE IN ANY CONSECUTIVE TWELVE (12) MONTH PERIOD. IF THE PATIENT IS ELIGIBLE FOR HIV GENOTYPE TESTING UNDER ADAP, THE PATIENT IS NOT ELIGIBLE TO RECEIVE THIS SERVICE UNDER RYAN WHITE TITLE I.

As the primary medical caretaker for _____ it is my considered opinion that he/she requires HIV genotypic resistance testing. The patient is not currently receiving antiretroviral medications and one of the following criteria has been met:

1. ____ The patient is antiretroviral-naïve, and therapy is being initiated for acute HIV infection. It is likely that resistance testing at baseline will optimize virological response.
2. ____ The patient is antiretroviral-naïve, and therapy is being initiated for chronic HIV infection present not more than 2 years. Resistance testing at baseline is recommended since some resistance-associated mutations are known to persist in the absence of drug pressure.
3. ____ The patient is antiretroviral-naïve, and there is a significant probability that he/she was infected with antiretroviral-resistant virus due to a specific history of apparent unprotected sexual exposure to an antiretroviral-experienced partner.
4. ____ Antiretroviral therapy (ART) is being initiated in a new patient, not previously known, who is not currently receiving antiretroviral therapy, but who gives a history of past antiretroviral exposure from another caregiver or institution.

I understand HIV genotypic resistance testing may only be ordered under the following conditions:

1. The applicable criterion above has been fully documented in the patient's medical record;
2. ART therapy and adherence have been discussed with the patient as part of his/her medical treatment;
3. The patient has acknowledged an understanding of treatment goals and expressed his/her intent to adhere to ART therapy;
4. The patient's plasma HIV RNA (viral load) at the time of testing must be at least 1000 co/ml.

Test ordered: ____ Genotype ____ Genotype with Data Base Match (Virtual Phenotype)

Sincerely,

_____, M.D.

Print Physician's name

Florida Medical License # (MEO#)

Patient's 10 digit Medicaid # (if applicable)

Patient's CIS # (assigned by the Ryan White Title I Service Delivery Information System)

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Rev. 02/14/05

**RYAN WHITE TITLE I PROGRAM
LETTER OF MEDICAL NECESSITY FOR
ANTIRETROVIRAL HIV GENOTYPE RESISTANCE ASSAYS: ANTIRETROVIRAL FAILURE**

Date: _____

A MAXIMUM OF TWO (2) ANTIRETROVIRAL RESISTANCE TESTS MAY BE ORDERED IN ANY TWELVE (12) MONTH CONSECUTIVE PERIOD TO INCLUDE NO MORE THAN ONE (1) HIV PHENOTYPE IN ANY CONSECUTIVE TWELVE (12) MONTH PERIOD. IF THE PATIENT IS ELIGIBLE FOR HIV GENOTYPE TESTING UNDER ADAP, THE PATIENT IS NOT ELIGIBLE TO RECEIVE THIS TEST UNDER RYAN WHITE TITLE I.

As the primary medical caretaker for _____ it is my considered opinion that he/she requires HIV genotypic resistance testing. The following criterion has been met:

1. _____ The patient has sub-optimal suppression of the viral load following initiation of antiretroviral therapy (ART) as defined by the current medical guidelines of the Department of Health and Human Services;
- OR**
2. _____ The patient has experienced virologic failure during combination ART as defined by the current medical guidelines of the Department of Health and Human Services.

I understand HIV genotypic resistance testing for antiretroviral failure may only be ordered under the following conditions:

1. The applicable criterion above has been fully documented in the patient's medical record;
2. It appears the patient has been fully adherent to his/her current antiretroviral treatment regimen;
3. Adherence has been discussed with the patient on an on-going basis as part of his/her medical treatment;
4. The patient's two most recent plasma HIV RNA (viral loads) must be at least 1000 copies/ml at the time of testing. At least one reading must be less than 3 months old;
5. The patient must be on antiretroviral medications at the time of testing or off medications no more than 2 weeks prior to testing.

Test Ordered: _____ Genotype _____ Genotype with Data Base Match (Virtual Phenotype)

Sincerely,

_____, M.D.

Print Physician's name

Florida Medical License # (MEO#)

Patient's 10 digit Medicaid # (if applicable)

Patient's CIS # (assigned by the Ryan White Title I Service Delivery Information System)

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Rev. 02/14/05

**RYAN WHITE TITLE I PROGRAM
LETTER OF MEDICAL NECESSITY FOR
ANTIRETROVIRAL PHENOTYPE RESISTANCE ASSAYS FOR EXPERIENCED PATIENTS
COVERAGE IS LIMITED TO A MAXIMUM OF ONE PHENOTYPE IN ANY CONSECUTIVE TWELVE MONTH PERIOD.**

Date: _____

As the primary medical caretaker for _____ it is my considered opinion that he/she requires HIV phenotypic resistance testing. The following criteria have been met:

1. The patient at any time in the past has failed two (2) or more antiretroviral (ARV) regimens;
2. Results of at least one, preferably more, prior genotype(s) must be available in the chart and Resistance to two or more drugs per class in at least two classes of ARVs is present on prior genotype(s);

AND ONE OF THE FOLLOWING (check-off the appropriate condition below):

- ☐ Prior genotype(s) show(s) resistance to at least 2 PIs other than ritonavir and use of a PI is being considered;
- OR**
- ☐ Lopinavir/ritonavir is being considered in a PI-experienced patient with four or more mutations associated with resistance to lopinavir/ritonavir on a prior genotype;
- OR**
- ☐ Four or more mutations at codons associated with PI cross-resistance are present;
- OR**
- ☐ M184V mutation is present in the presence of 3 or more NRTI-associated mutations (NAMs);
- OR**
- ☐ K65R mutation is present, or other mutations associated with NRTI cross-resistance (69 insertion complex or 151 complex);
- OR**
- ☐ Rescue ARV regimens guided by results of two or more prior genotypes have failed to suppress viral replication, whether mutations present or not, and the patient has been determined to be adherent on re-evaluation. (Requires a minimum of two prior genotypes.)

I understand HIV phenotypic resistance testing for experienced patients may only be ordered under the following conditions:

1. The above criteria have been met and are fully documented in the patient's medical record;
2. Adherence has been discussed with the patient on an on-going basis as part of his/her medical treatment, and it has been determined that the patient is fully adherent with his/her current ART regimen;
3. The patient's plasma HIV RNA (viral load) at the time of testing must be at least 1000 co/ml within the past month (attach copy to letter of medical necessity);
4. The patient must be on antiretroviral medications at the time of testing.

Sincerely,

_____, M.D.

Print Physician's name

Florida Medical License # (MEO#)

Patient's 10 digit Medicaid # (if applicable)

Patient's CIS # (assigned by the Ryan White Title I Service Delivery Information System)

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Rev. 02/14/05